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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/801,277	03/16/2004	Staley Brod	D5716CIP4/C	6125
<div>52034      7590      09/18/2007 FULBRIGHT &amp; JAWORSKI, L.L.P. 600 CONGRESS AVENUE SUITE 2400 AUSTIN, TX 78701</div>				
			EXAMINER SEHARASEYON, JEGATHEESAN	
			ART UNIT 1647	PAPER NUMBER
			MAIL DATE 09/18/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

Application No.

10/801,277

Applicant(s)

BROD, STALEY

Examiner

Jegatheesan Seharaseyon, Ph.D

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 06 July 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 19-30 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 19-30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

1. This Office Action is in response to Applicant's remarks and amendments filed 7/06/2007. Claims 19-30 are pending. Claims 19, 21, 22, 23 and 25-30 have been amended. Therefore claims 19-30 are examined.

2. Any objection or rejection of record, which is not expressly repeated in this action, has been overcome by Applicant's response and withdrawn.

3. The Office notes that Applicant has amended the specification to capitalize trademarks.

4. Applicant has also amended the title.

5. The Applicant has failed to comply with the requirements of the sequence rules (see pages 68 and 69). Applicant must append SEQ ID Nos. to all mentions of specific sequences in the specification and the claims. See 37 CFR § 1.821(d). The Office may hold the Applicant non-responsive if Applicant does not comply with the requirements of the sequence rules.

6. The Office in the Office Action mailed 4/12/07 had required the Applicant to update the priority information by filing an amendment to the first sentence(s) of the specification or an ADS. See MPEP § 201.11. The Office may hold the Applicant non-responsive if Applicant does not update the priority information in the next response.

### ***Claim Rejections - 35 USC § 112***

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7a. Claim 19-30 remains rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is maintained. It is unclear in claims 20, 24 and 30 the amount administered is in units or international units. The claims recite 30,000 units, but it is unclear if this should be "units" or "international units". Further, it is not clear if the dosage administered is per Kg or total dose administered. Therefore, the rejection of record is maintained.

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8a The rejection of claims 19-22 under 35 U.S.C. 112, first paragraph, because the specification while enabling for treating destructive joint disease associated with rheumatoid arthritis in an individual or reducing inflammation associated with rheumatoid arthritis or reducing the level of interleukin in an individual with rheumatoid arthritis by oral administration of IFN- $\alpha$ , does not reasonably provide enablement for the preventing destructive joint disease associated with rheumatoid arthritis in an individual. Is maintained for reasons set forth in the Office Action dated 4/12/2007 pages 4-6.

Applicant has traversed the rejection and argues that example 36 demonstrates a substantial improvement (via halting of progression) in terms of both joint pain and joint swelling. Thus, it is claimed that the rationale for the studies was to demonstrate usefulness in preventing the development of destructive joint disease. Applicant also argues that the examiner has presented no reasoning or evidence to the contrary to

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question the truthfulness of the above statement. Applicant's arguments have been fully considered but are not found to be persuasive. Although, example 36 demonstrates that interferon alpha administration reduces, for example IL-8 secretion in some patients, there is no evidence in the specification or the prior art to indicate that the administration of interferon alpha prevents destructive joint disease associated with rheumatoid arthritis in an individual. As Applicant indicated in the response (page 6), while there was substantial improvement (via halting of progression) in terms of both joint pain and joint swelling, there is no evidence for preventing destructive joint disease associated with rheumatoid arthritis.

Applicant on page 6 of the response citing MPEP § 2164.04 argues that the initial burden to establish a reasonable basis to question the enablement with acceptable evidence or reasoning must be provided by the Examiner. Applicant also argues that that Examiner's arguments fail to establish a reasonable basis to question the enablement. The Examiner did provide the reasons to question the claimed invention on pages 4-6 of the Office Action dated 4/12/2007. According to In re Bowen, 492 F.2d 859, 862-63, 181 USPQ 48, 51 (CCPA 1974), the minimal requirement is for the examiner to give reasons for the uncertainty of the enablement. The examiner concluded based on the lack of disclosure in the specification how to use the claimed invention to prevent destructive joint disease associated with rheumatoid arthritis by administering IFN- $\alpha$  contemplated by the Applicant, that the specification fails to teach how to make and use the claimed invention without undue experimentation, or that the

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scope of any enablement provided to one skilled in the art is not commensurate with the scope of protection sought by the claims.

Further, contrary to Applicant's assertion that the Office has not established that there is reasonable basis to question the scope of enablement; Office did provide Shiozawa et al. 1992 reference, which clearly teaches the treatment of rheumatoid arthritis but not the prevention of destructive joint disease associated with rheumatoid arthritis (although, the improvement of clinical indices are taught there is no evidence or guidance with respect to the prevention of destructive joint disease associated with rheumatoid arthritis). As indicated previously, the specification fails to provide guidance with respect to what patient population will be selected for the preventing destructive joint disease associated with rheumatoid arthritis by administering IFN- $\alpha$ . In addition, if a patient population with the "disease symptoms" are identified, the onset of disease has taken place, thus the pathology cannot be prevented (only further progression maybe stopped).

Further, because there is inadequate guidance as to the nature of the invention, it is merely an invitation to the artisan to use the current invention as a starting point for further experimentation for preventing destructive joint disease associated with rheumatoid arthritis by administering IFN- $\alpha$  orally. In addition, because there are no working examples provided describing prevention of diseases or models it would require an undue amount of experimentation to one of skill in the art to practice the claimed invention.

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As indicated previously, given the breadth of claims 19-22 in light of the unpredictability of the art as determined by the lack of working examples, the level of skill of the artisan, and the lack of guidance provided in the instant specification and the prior art of record, it would require undue experimentation for one of ordinary skill in the art to make and use the claimed invention for a method of preventing destructive joint disease associated with rheumatoid arthritis by administering IFN- $\alpha$  orally. Therefore, the rejection of record is maintained.

***Claim Rejections - 35 USC § 103***

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9a. The rejection of claims 19-26 under 35 U.S.C. 103(a) as being unpatentable over Shozawa et al. (1992) in view of Cummings (U.S. Patent No: 4, 497, 795) and Cummings (U.S. Patent No: 5, 019, 382) for reasons set forth in the Office Action dated 4/12/2007 (pages 7-8).

Shozawa et al. (1992) reference was introduced in the Office Action dated 4/12/2007 (page 7) to teach the teaching of administering IFN- $\alpha$  to treat rheumatoid arthritis (treatment of rheumatoid arthritis will inherently treat destructive joint disease associated with rheumatoid arthritis). Cummings '795 patent was introduced to teach the oral administration and dosage (Office Action dated 4/12/2007, page 8). Cummings '382 patent teaches the conversion of international units to units. Applicant is arguing the references individually. Specifically, Applicant is asserting that Shozawa reference does not teach oral administration. Similarly, Applicant is asserting that "795 teaching are irrelevant and '382 patent teaches non-obviousness. Applicant's arguments have been fully considered but are not found to be persuasive. With reference to Applicant's arguments that '382 patent teaches substantially lower dose, this again is not found to be persuasive because it is the combined teaching which makes it obvious over prior art. Contrary to Applicant's assertion that the references individually do not teach the instant invention, the combined teaching does teach the instant invention of preventing destructive joint disease associated with rheumatoid arthritis by administering IFN- $\alpha$  orally as indicated in the Office Action dated 4/12/2007 pages 7 and 8. In addition, courts have held that it is not necessary that the claimed invention be expressly suggested in any one or all of the references to justify combining their teachings; rather the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art, *In re Keller*, 642 F.2d 413, 288 USPQ 871 9ccpa 1981). In addition, the motivation to combine can arise from the expectation that the prior art elements will perform their expected functions to achieve their expected results when



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combine for their common known purpose. Section MPEP 2144.07. With reference to Applicant's argument that the dosage taught by these references falls outside the scope of the claimed invention, MPEP 2144.05 [R-5] states that generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955) (Claimed process which was performed at a temperature between 40°C and 80°C and an acid concentration between 25% and 70% was held to be prima facie obvious over a reference process which differed from the claims only in that the reference process was performed at a temperature of 100°C and an acid concentration of 10%.); see also Peterson, 315 F.3d at 1330, 65 USPQ2d at 1382 ("The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages."). Thus, optimization of the dosage is considered obvious over prior art. Therefore, the rejection of record is maintained.

9b. The rejection of claims 27-30 under 35 U.S.C. 103(a) as being unpatentable over Shozawa et al. (1992) in view of Cummings (U.S. Patent No: 4, 497, 795) and Cummings (U.S. Patent No: 5, 019, 382) further in view of Aman et al. (1994) is also maintained for reasons set forth in the Office Action dated 4/12/2007 (pages 8-9).

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Applicant is traversing the rejection for reasons set forth above in 9a.. In addition, Applicant contends that Aman et al reference fails to modify the other teachings. Contrary to Applicant's assertions the combined teaching teaches the instant invention for reasons set forth above in paragraph 9a and the Office Action dated 4/12/2007. Therefore, the rejection of record is maintained.

### **Conclusion**

10. No claims are allowable.

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

### **Contact Information**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jegatheesan Seharaseyon, Ph.D whose telephone number is 571-272-0892. The examiner can normally be reached on M-F: 8:30-5:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath N. Rao, Ph. D can be reached on 571-272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JS  
Art Unit 1647  
September 16<sup>th</sup>, 2007

**CHRISTINE J. SAOUD  
PRIMARY EXAMINER**

*Christine J. Saoud*